

**CYLINDRICAL LIGHT DIFFUSER
Model RD-ML
Instructions for Use**

PRODUCT DESCRIPTION

RD-ML cylindrical light diffuser is a catheter type device based on a fiber optic. A standard optical connector is fixed at the proximal end of the catheter. The distal end of the catheter is a diffusing optical tip. RD-ML models with different tip lengths are available (Model RD-MLxx, with xx is the length of the diffusing tip, in mm). Connected to a laser source, the RD-ML cylindrical light diffuser guides light of low intensity from the laser to its distal end, where the light is uniformly distributed along the optical tip.

INTENDED USE

RD-ML cylindrical light diffuser is suitable for controlled illumination of biological tissues with low intensity. It is intended for use in photodynamic therapy (PDT) in a Positioning Catheter Needle with an approved PDT protocol

This device is used in conjunction with laser light during PDT and should only be used with compatible lasers.

RD-ML cylindrical light diffuser is used in endoscopic sites (aero-digestives tract, and GI tract, bronchus, bladder, uterus, etc.), externally (skin, oral cavity) or in post-operative sites. The devices should not be used in liquid with very high scattering and low absorption properties, such as Intralipid.

This device is supplied sterile and is intended for single-use only.

CAUTION: The device is not designed for re-use. The cleaning with standard clinical cleaning procedure by untrained personnel can damage the device. The damage cannot be detected without specific equipment and can reduce the efficacy of the treatment.

CAUTION: The device cannot be re-sterilized with standard EtO sterilization procedure. Medlight S.A. sterilizes the device with a validated specific EtO sterilization procedure.

CAUTION: Do not use this device for any purpose other than the stated intended use. The device should not be used in contact with central circulatory system and with central nervous system.

CONTENTS OF PACKAGE AND STORAGE CONDITIONS

The package contains one RD-ML cylindrical light diffuser intended for use in photodynamic therapy. Store the device in its Medlight S.A. original box, in a cool dark dry location.

EQUIPMENT REQUIRED

RD-ML cylindrical light diffuser.
Laser with calibration unit and protective eyewear (not included)
Photodynamic therapy drug with protocol (not included).

WARNINGS

THESE INSTRUCTIONS ARE INTENDED FOR USE BY PHYSICIANS WHO HAVE BEEN TRAINED IN THE USE OF PHOTODYNAMIC THERAPY (PDT) WITH AN APPROVED PDT DRUG AND APPROPRIATE LASER SYSTEM.

THESE INSTRUCTIONS ARE APPLICABLE ONLY TO THE RD CYLINDRICAL LIGHT DIFFUSER USED IN CONJUNCTION WITH AN APPROVED PDT DRUG AND APPROPRIATE LASER SYSTEM FOR PDT. INSTRUCTIONS FOR USE OF THE FIBER OPTIC, THE PHOTOSENSITIZING PDT DRUG AND THE SELECTED LASER SYSTEM SHOULD BE READ CAREFULLY BEFORE USE.

FOLLOW THE LASER MANUFACTURER OPERATING MANUAL FOR LASER INSTALLATION AND OPERATION.

USE OF INCOMPATIBLE LASERS THAT ALTER THE REQUIRED LIGHT OUTPUT CHARACTERISTICS FOR THE PHOTOACTIVATION OF THE

PDT DRUG COULD RESULT IN INCOMPLETE TREATMENT DUE TO PARTIAL PHOTOACTIVATION OF THE PDT DRUG, OVERTREATMENT DUE TO OVERACTIVATION OF THE PDT DRUG, DAMAGE TO SURROUNDING NORMAL TISSUE AND/OR DAMAGE TO THE FIBER OPTIC WHICH COULD ADDITIONALLY CREATE AN OPTICAL HAZARD FOR MEDICAL PERSONNEL AND/OR THE PATIENT.

COMPLY WITH FACILITY LASER SAFETY REQUIREMENTS.

ENSURE THAT ALL PERSONNEL ARE AWARE OF FIBER OPTIC HANDLING IN CONJUNCTION WITH THE LASER AND ARE TAKING PROPER PRECAUTIONS.

ALWAYS WEAR PROTECTIVE EYEWEAR DURING LASER LIGHT DELIVERY. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION. DO NOT VIEW THE LASER BEAM DIRECTLY, EVEN WHILE WEARING PROTECTIVE EYEWEAR. PROVIDE EYE PROTECTION FOR PATIENT IN ADDITION TO ALL OPERATING ROOM STAFF.

DO NOT EXCEED MAXIMUM FIBER OUTPUT POWER SPECIFICATION

PREPARATION FOR USE

1. Prepare the laser system for delivery of light of the specified wavelength for photoactivation of the PDT drug as indicated in the appropriate laser system operating manual.

CAUTION: Verify that the output characteristics of the laser match the input characteristics of the fiber, to assure uniform light distribution from the cylindrical diffuser as required for the photoactivation of the PDT drug.

2. Remove the cylindrical light diffuser from its package, after verification of the shelf-life of the device. Uncoil slowly and carefully the catheter. Inspect the fiber for visible signs of damage. Securely attach the optical connector to the laser fiber port.

CAUTION: Fragile device, contains optical fiber that may break if handled roughly or bent sharply.

CAUTION: Keep the optical connector clean. Avoid touching the optical connector surface, as this may stain or scratch the optical surface of the laser connector.

3. Calibrate the fiber output using the laser calibration unit (integrating sphere), according to the procedure described in the laser system operating manual, or a suitable external calibration unit.

CAUTION: If the calibration procedure gives unexpected results (for example, fiber transmission lower than specified), do not continue without investigating the cause for the apparent high energy loss. Possible causes may include inappropriate laser source, laser out of alignment, dirty cuvette into calibration unit, incorrect setting or malfunction of the calibration unit, defect or break in the fiber optic, dirty optical connector, stained or damaged optical diffusing tip.

CAUTION: Where applicable, be sure to perform calibration procedure in sterile condition. Use of a sterile cuvette is necessary to assure fiber sterility.

4. Set the laser to emit low power (aiming beam) and check the light uniformity along the diffusing tip. If the illumination does not appear uniform, switch off the laser and inspect the optical tip for dirt or damage. Do not use the fiber if the output uniformity pattern is not acceptable or if damage is evident.

5. Follow the PDT drug protocol to determine the required light dose needed for the expected PDT outcome. Adjust the power output of the laser to that required for the treatment.

CAUTION: Do not exceed maximum fiber power specification when adjusting laser power. Setting the laser power beyond

specified levels may result in overtreatment or damage the fiber optic.

Do not use the device into Intralipid or similar medium with high scattering and low absorption properties.

PROCEDURE

1. Position the RD-ML cylindrical light diffuser in the organ to be treated following the instructions of the approved PDT protocol.

CAUTION: Avoid tissue residue, blood and/or expectoration to stain the optical tip. This may cause excessive light absorption and thus damage the optical tip of the device.

Avoid bending of the optical tip during the treatment.

2. Begin light treatment by depressing the laser footswitch / handswitch. Release the laser footswitch / handswitch when the treatment is complete.

CAUTION: Avoid inadvertent photoactivation of non-target tissue. Ensure that surrounding areas are shielded from laser light.

3. If a treatment area requires more than one illumination, reposition the cylindrical light diffuser over the next treatment area. Avoid overdosing with laser light by minimizing overlapping of treatment areas.

4. Discard the device after use.

CAUTION: Do not clean the device for re-use or re-sterilization. The device is not designed for reprocessing.

DEVICE CHARACTERISTICS:

RD-ML CYLINDRICAL LIGHT DIFFUSER

MECHANICAL (APPROXIMATE)	RD-MLxx
TIP DIAMETER	1.000 mm
OVERALL LENGTH	3.0 m
OPTICAL	
TYPICAL TRANSMISSION (*)	80 %
ILLUMINATION LENGTH	xx [mm]
UNIFORMITY	± 15%
MAXIMUM POWER DENSITY (in air)	0.5 W/cm (cw)
ABSOLUTE MAXIMUM INPUT POWER	2.0 W (cw)
OPTICAL FIBER	
FIBER MATERIAL	SILICA, low OH ⁻
CORE DIAMETER	400 µm
NUMERICAL APERTURE (NA)	0.37
MINIMUM BENDING RADIUS (long term)	47 mm
OPTICAL CONNECTOR	SMA-905
CONDITIONING	
PACKAGING	DOUBLE POUCHES INDIVIDUAL BOX
STERILIZATION	STERILE / EtO
USEFUL LIFE	
RE-USE	DISPOSABLE
SHELF LIFE	2 YEARS
MISCELLANEOUS	
RADIOMARKERS	OPTIONAL

(*) Transmission is defined in comparison with a 3 m / 400µm / NA0.37 silica bare fiber.

SYMBOLS



LEGAL MANUFACTURER



COUNTRY OF MANUFACTURE



SERIAL NUMBER



DATE OF MANUFACTURE



USE-BY-DATE



UNIQUE DEVICE IDENTIFIER



MEDICAL DEVICE



CONSULT INSTRUCTION FOR USE



LASER RADIATION. AVOID DIRECT EYE EXPOSURE



DO NOT USE IF PACKAGE IS DAMAGED



DO NOT RE-USE



DOUBLE STERILE BARRIER SYSTEM



STERILIZED USING ETHYLENE OXIDE

DISCLAIMER OF WARRANTIES

Medlight S.A. product warranties and liability are limited in accordance with the Medlight S.A. Terms and Conditions of Sale which states, among other things, that the warranties are not effective if the user misuses the product in any manner, has failed to use the product in accordance with industry standards and practices, or has failed to use the product in accordance with its instructions for use.

In no case can Medlight S.A. be held responsible for an incorrect light dose applied during a PDT treatment.

VIGILANCE

In case of any serious incident that has occurred in relation to the device, it should be reported without any delay to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

LEGAL MANUFACTURER

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